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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,856	12/02/2003	Sharat Singh	033.06-1US	5950

33603 7590 06/21/2006

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EXAMINER

TUNG, JOYCE

ART UNIT PAPER NUMBER

1637

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/726,856	Applicant(s) SINGH ET AL.	
	Examiner Joyce Tung	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/18/05 & 4/04/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The preliminary amendment filed 12/2/2003 has been entered. Claims 11-20 are pending.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 11-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,686,152. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 11-20 are drawn to a method for detecting the presence or absence of one or more polynucleotides in a sample excluding uncleaved electrophoretic probes from an electrophoretic separation, while the claims 1-11 of U.S. Patent No. 6,686,152 are drawn to a method for detecting the presence or absence of one or more polynucleotides in a sample including the excluding step recited in claim 1. The differences between the patent and the instant claims are that the instant claim 11 recites that the capture agent confers on the undigested electrophoretic

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probes a charge that causes the undigested electrophoretic probes to migrate upon electrophoretic separation in a direction opposite of the e-tag reporters, thereby excluding the undigested electrophoretic probes. Thus the instant claims are an obvious variation over claims 1-11 of U.S. Patent No. 6,686,152. Therefore, nonstatutory obviousness-type double patenting is applicable.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5470705, issued November 28, 1995) in view of Babon et al. (5,851,770, issued Dec. 22, 1998).

Grossman et al. disclose a method of detecting a plurality of different sequences in a target sequence involving the use of a plurality of sequence probes (See column 2, lines 54-56). The probe used in the method has the features of the electrophoretic probe cited in claims 14 and

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19. The probe includes a binding polymer, a polymer chain that imparts to that probe, a distinctive ratio of charge/translational frictional drag and a reporter attached to the binding polymer (See column 20, lines 52-57). The binding polymer is an oligonucleotide including at least 10-20 bases allowing hybridization to the target polynucleotide (See column 6, lines 66-67 and column 7, lines 1-10). This teaching is inherent that the target polynucleotide is in the range of from 5-100 polynucleotide as recited in claim 15. Other binding polymers are analogs of polynucleotides, such as deoxynucleotides with thiophosphodiester linkage (See column 7, lines 11-19). The polymer chain has a ratio of charge/translational frictional drag, which is evidenced by a distinctive electrophoretic mobility in a non-sieving matrix (See column 7, lines 50-64). The polymer chain can be polyethylene oxide (PEO) or a polypeptide chain where the chains are attached to different-sequence binding polymers (See column 3, lines 11-18). The teachings suggest that the charge/translational frictional drag is consisted of carbon, hydrogen, oxygen, phosphorus, nitrogen, sulfur and boron. The charge of the polymer is the total net electrostatic charge of the polymer at a given pH (See column 6, lines 15-16). It is inherent that the probes have a positive charge or a negative charge based upon the given pH. The label refers to a fluorophore or chromophore (See column 6, lines 39-44). The features of Grossman et al.'s probe suggest the features of the claimed e-tag probe.

Grossman et al. do not explicitly disclose the molecular weight of the mobility modifier, which is 1 to 300 atoms or 30-3000 dalton, or from 35-1500 daltons. However, the binding polymer and polymer chain contribute to the mobility modifier of probe (See column 3, lines 55-64.). The polymer chain may be polyethylene oxide (PEO) or a polypeptide chain (See column 3, lines 11-18, column 7, lines 39-49). Since these molecules are small molecules, the teachings

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are inherent that the molecular weight of the mobility modifier would be from 1 to 300 atoms or from 30-3000 daltons or from 35-1500 daltons.

Grossman et al. also do not explicitly disclose that e-tag reporter has a molecular weight of from 150-10,000 daltons. However, the e-tag is defined in claims 14-15 and 19 containing mobility modifier. As discussed in the previous paragraph regarding the molecular weight of mobility, the teachings of mobility modifier read on the limitation regarding the molecular weight of e-tag.

Grossman et al. do not explicitly disclose a capture agent that specifically binds the capture ligands of the electrophoretic probes and confers on the undigested electrophoretic probes a charge that causes the undigested electrophoretic to migrate upon electrophoretic separation in a direction opposite of that of the e-tag reporters, thereby excluding said undigested electrophoretic probes from the electrophoretic separation of the released e-tag as recited in claim 11, and the capture ligand and the capture agent recited in claims 17-18 and 20.

Babon et al. disclose a method for detecting on or more mismatches between a first and second nucleic acid in which the heteroduplex formed between the first and second nucleic acid sequence is biotinylated and captured by binding to streptavidin-magnetic beads (See column 7, lines 53-66) and the captured heteroduplex are then cleaved, the cleaved fragment is analyzed by gel electrophoresis (See column 8, lines 1-4). The capture ligand and capture agent includes antigen/antibody or DNA binding protein and its DNA binding site (See column 18, lines 13-24).

Nevertheless, Babon et al. do not explicitly disclose the capture agent which confers on the undigested electrophoretic probes a charge that causes the undigested electrophoretic to migrate upon electrophoretic separation in a direction opposite of that of the e-tag reporters, thereby excluding said undigested electrophoretic probes from the electrophoretic separation of

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the released e-tag as recited in claim 11. However, the claims further recite the capture ligands and agents in claims 17-18 and 20, which are the same capture ligands and agents used in the method of Babon. This is inherent that the capture ligands and agents would have the same function as recited in claim 11.

One of ordinary skill in the art at the time of the instant invention would have been motivated to modify the method of Grossman et al. by using the capture ligand/agent attached to the oligonucleotide probe as taught by Babon et al. because by using this technique, the background signal is dramatically reduced, thereby increasing the sensitivity and specificity of the mismatch cleavage assay (See column 7, lines 27- 37). Thus, it would have been prima facie obvious to apply the capture ligands and agents as recited in claims 17-18 and 20.

Summary

5. No claims are allowable.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung *J. Tung*
June 7, 2006

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
6/15/06